

REMARKS

Restriction is proper only if the restricted claims are independent or patentably distinct and there is no serious burden placed on the Examiner if restriction is not required (MPEP §803). The burden is on the Examiner to provide reasons and/or examples to support any conclusion of patentable distinctness between the restricted claims (MPEP §803). Applicant respectfully traverses the restriction requirement on the grounds that the Office has not carried the burden of providing any reasons and/or examples to support the conclusion that the claims of the restricted groups are, in fact, distinct.

The Office has characterized the relationship between the claims reciting RNase inhibitor proteins and types of RNase as being unrelated. Applicants note that this aspect of the restriction/election of species is improper on its face because the claims are directed to methods, not compositions of matter. Both restriction requirements and election of species requirements must be based on the invention as claimed. The invention as claimed is a method; thus the elements of the claimed invention are the verbs presented in the claims, not the nouns. Therefore, this portion of the restriction/election of species is improper.

The Office also states, in support of this portion of the restriction/election that "where structural identity is required, such as for hybridization or expression, the polypeptides have different effects." Applicants respectfully note that the claims do not require, as a positively recited step, either hybridization or expression. Thus, the Office's statement is irrelevant to the claims presented. A restriction requirement must be based upon the invention as it is claimed, not on some other, unrelated basis.

For claims to be found unrelated, the Office must show both that the claims are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects. Because the Office has not carried its burden to establish that the groups of claims as identified by the Examiner are unrelated, Applicants submit that the restriction/election of species based on unrelatedness is improper. Withdrawal of this portion of the restriction/election requirement is respectfully requested.

The Office also appears to take the mutually exclusive position that the inventions of Group I and II are "related," but mutually exclusive and therefore patentably distinct.

Applicants traverse this restriction requirement because the reasons noted by the Office are insufficient to support the conclusion that the claims of the restricted groups are patentably distinct. The Office states that the method of Group II result in the ultimate synthesis of a nucleic acid product, but that the method of Group I "merely" protects or maintains a nucleic acid product. The Office does not articulate, however, why that outcome renders the claims patentably distinct. Applicants therefore submit that the restriction requirement is improper. Withdrawal of the same is respectfully requested.

In the same fashion as a restriction requirement, an election of species requirement is proper only if the restricted species are independent or patentably distinct **and** there is no serious burden placed on the Office if an election is not required (MPEP §803). The burden is on the Office to provide reasons and/or examples to support any conclusion of patentable distinctness between the restricted species (MPEP §803). Applicant respectfully traverses the election of species requirement on the grounds that the Office has not carried the burden of providing any reasons and/or examples to support the conclusion that the restricted species are, in fact, patentably distinct. In the present instance, the Office has not provided any reasons or examples as to why the methods **as claimed**, would be patentably distinct from one another when practiced using any type or RNase inhibitor protein that was capable of inhibiting the RNases present in the mixture. Therefore, the election of species requirement is improper.

With regard to election of species requirements involving Markush-type claims, the Examiner's attention is directed to MPEP §803.02:

If the members of the Markush groups are sufficiently few in number or so closely related that a search and examination of the entire claim can be made without serious burden, the examiner **must** examine all claims on the merits, even though they are directed to independent and distinct inventions. In such a case the, examiner will not follow the procedure described below and **will not** require restriction.

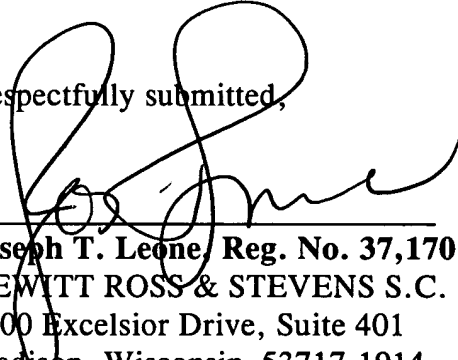
In the present case, Applicants respectfully note that the Markush recitation of Claim 5 (for example) recites only four sources of the RNase inhibitor protein. Claim 9 (for example) also recites only four types of RNases. A four-member Markush group, wherein all

four species are RNase inhibitor proteins (or RNases themselves), is an exceedingly small and well-contained group. Therefore, Applicants respectfully submit that MPEP §803.02, quoted above, controls and the election of species requirement is improper.

Accordingly, because the Office has not carried the burden of providing technologically sound reasons or examples for concluding that the restricted species are patentably distinct, the election of species requirement is improper and should be withdrawn.

Applicants submit that the application is now in condition for examination on the merits. Early notification of such action is earnestly solicited.

Respectfully submitted,


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RNasin® Plus RNase Inhibitor is a recombinant mammalian RNase inhibitor purified by a combination of ion exchange and hydrophobic interaction chromatography to yield a purity >90%. This protein is capable of inhibiting eukaryotic RNases (e.g., RNase A and RNase B) similar to human placental RNase inhibitor.


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